Express Mail No. EV 889007786US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of: Examiner: Alvin J. Stewart

Gene Michal Art Unit: 3738

Serial No: 10/712,678

Filed: November 12, 2003

For: Ethylene-Carboxyl Copolymers As Drug Delivery Matrices

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This Appeal Brief is submitted pursuant to receipt of an Advisory Action mailed on April 11, 2007, in which the examiner maintained his rejection of independent claims 44-54.

REAL PARTY IN INTEREST

The real party in interest with regard to this appeal is Advanced Cardiovascular Systems Inc., a California corporation, having a place of business at 3200 Lakeside Drive, Santa Clara, California 95054. The original assignment to Advanced Cardiovascular system Inc. was recorded at Reel/Frame 011694/0183 on June 27, 2001. Effective February 13, 2007, Advanced Cardiovascular Systems Inc. changed its name to Abbott Cardiovascular Systems Inc.

RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences related to or that might have any bearing, direct or indirect, on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 44-54 are pending in the application.

Claims 44-54 are rejected and form the subject of this appeal.

Claims 37-49 were initially filed in this case as a divisional application of U.S. application No. 09/748,719, filed December 22, 2000, issued as U.S. Patent No. 6,824,559. Claims 37 and 44 are independent claims. Claims 38-43 depend from claim 37, and claim 45-49 depend from claim 44. In an office action mailed October 4, 2004 (**Evidence Appendix, "A"**), claims 37-49 were rejected as being obvious over U.S. Patent No. 6,379,379 to Wang ("Wang ") (**Evidence Appendix, "B"**) in view of U.S. Patent No. 4,142,526 to Zaffaroni et al. ("Zaffaroni") (**Evidence Appendix, "C"**). Applicant responded on January 4, 2005, pointing out that Zaffaroni does not describe or teach (1) an ethylene-carboxylic acid copolymer and (2) a copolymer with 5-50 wt% of carboxylic acid monomer (**Evidence Appendix, "D"**). Applicants argued that claims 37-49 are non-obvious over Wang in view of Zaffaroni.

On March 22, 2005, the examiner issued another office action (**Evidence Appendix, "E"**), in which the examiner allowed claims 44-49, but again rejected claims 37-43 as being anticipated by U.S. Patent No. 6,738,661 to Nyhart, Jr. under 35 U.S.C. 102(e) ("Nyhart") (**Evidence Appendix, "F"**). The examiner argued that Medtronic describes a polymer coating composition having a heparin adduct and further comprising poly(ethylene glycol) chains. Applicants responded on June 29, 2005

(**Evidence Appendix, "G"**), pointing out that Nyart does not describe or teach (1) an ethylene-carboxylic acid copolymer and (2) a copolymer with 5-50 wt% of carboxylic acid monomer. Applicants argued that Nyart does not anticipate claims 37-43. On June 29, 2005, a notice of non-compliant amendment was mailed, indicating that the response filed by Applicants on June 22, 2005 fails to provide a list of claims and the claims were not presented in ascending numerical order (**Evidence Appendix, "H"**). Applicants addressed the non-compliance issues by a communication mailed on July 7, 2005 (**Evidence Appendix, "I"**).

On September 29, 2005, the examiner mailed an office action (**Evidence Appendix, "J"**), withdrawing the rejections of claims 37-43 over Nyart, but rejecting these claims as being anticipated by U.S. Patent No. 5,401,512 to Rhodes ("Rhodes") (**Evidence Appendix, "K"**) under 35 U.S.C. 102(b). Applicants responded on November 30, 2005, amending claim 37 to additionally recite "wherein the copolymer is a coating on an implantable substrate" (**Evidence Appendix, "L"**). Applicants pointed out that Rhodes describes "an orally administrable formulation for selectively administering the drug to the large intestine" but fails to teach or suggest all the limitations of Claim 37 and that claims 37-43 are thus allowable over Rhodes. On December 14, 2005, a notice of non-compliant amendment was mailed, indicating that the response filed by Applicants on November 30, 2005 fails to provide to a proper status identifier to the claims (**Evidence Appendix, "M"**). Applicants addressed the non-compliance issues by a communication mailed on January 6, 2006, in which Applicants also canceled claim 43 and added new claims 50-55 (**Evidence Appendix, "N"**).

On March 22, 2006, the examiner mailed a final office action (**Evidence Appendix, "O"**), allowing claims 44-54, and rejecting claims 37-42 and 55 as being anticipated by Rhodes under 35 U.S.C. 102(b). The examiner alleged that the limitation "wherein the copolymer is a coating on an implantable substrate" is functional and thus would not add patentability weight to the claims. Applicants responded on May 8, 2006, amending the claims to recite "a drug delivery coating on an implantable medical device" instead of "a drug delivery matrix" (**Evidence Appendix, "P"**). Applicants pointed out that Rhodes fails to provide a drug delivery coating. On May 25, 2006, the examiner mailed an advisory action (**Evidence Appendix, "Q"**), refusing to enter the

amended claims. On June 2, 2006, Applicants filed a supplemental response to final office action, canceling all the rejected claims, claims 37-42 and 55 (**Evidence Appendix, "R"**).

On August 24, 2006, the examiner mailed an office action (**Evidence Appendix, "S"**), rejecting claims 50-52 as indefinite, rejecting claims 44-46 and 53-54 as being anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang II") (**Evidence Appendix, "T"**) under 35 U.S.C. 102(b), and rejecting claims 47, 48 and 50-52 over Wang II in view of U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek") (**Evidence Appendix, "U"**) and claim 49 over Wang II in view of U.S. Patent No.4,729,914 to Kliment et al. ("Kliment") (**Evidence Appendix, "V"**) as being obvious under 35 U.S.C. 103(a). Applicants responded on November 7, 2006, pointing out that Wang II describe a composition that includes (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of acrylic or methacrylic acid but not a copolymer of an ethylene comonomer with a carboxylic acid comonomer (**Evidence Appendix, "W"**). Applicants further pointed that both Chabrecek and Kliment fail to provide a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Applicants argued that claims 44-54 are allowable.

On February 12, 2007, the examiner mailed a final office action (**Evidence Appendix, "X"**), maintaining the rejections of claims as set forth in the Office Action mailed on August 24, 2006. The examiner further rejected claims 44-54 as failing to comply with the written description requirement. Applicants responded on March 21, 2007, in which Applicants amended the specification to make the claims to comply with the written description requirement but did not amend the claims. Applicants again pointed out that none of Wang II Chabreck and Kliment describe or teach a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Applicants again argued that claims 44-54 are allowable.

On April 11, 2007, the examiner mailed an advisory action (**Evidence Appendix, "Y"**), maintaining the rejections of claims as set forth in the Final Office Action mailed on February 21, 2007.

Amendments in the response to Final Office Action filed on March 21, 2007 have been entered. Thus, claims 44-54 as pending on March 21, 2007, are the subject of this appeal.

STATUS OF AMENDMENTS

As indicated above, amendments in the Response to Final Office Action filed January 8, 2007 and prior amendments have been entered and are before the Board.

SUMMARY OF THE CLAIMED SUBJECT MATTER

The claimed invention relates to a method of coating an implantable medical device. Claim 44 is the sole independent claim, which succinctly set forth the invention:

> 44. A method of coating an implantable medical device, comprising:
> adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition;
> applying the composition to an implantable medical device; and
> allowing the solvent system to evaporate.

Support for claim 44 is found at least at page 3, line 21 to page 4, line 4; and page 17, line 21 to page 18, line 7 (Example 9) of the specification.

Claims dependent from claims 44 further define the scope of the invention in different aspects. The complete claim set as currently entered is provided in the **Claims Appendix**.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented in this appeal are:

(1) Whether claims 44-46 and 53-54 are anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang II") (**Evidence Appendix, "T"**) under 35 U.S.C. 102(b);

(2) whether claims 47, 48 and 50-52 are obvious over Wang II in view of U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek") (**Evidence Appendix, "U"**) under 35 U.S.C. 103(a); and

(3) whether claim 49 is obvious over Wang II in view of U.S. Patent No.4,729,914 to Kliment et al. ("Kliment") (**Evidence Appendix, "V"**) under 35 U.S.C. 103(a).

ARGUMENT

(1). Claims 44-46 and 53-54 are allowable over U.S. Patent No. 5,631,328 to Wang II under 35 U.S.C. 102(b)

A. The Law

Anticipation is established only when a single prior art reference discloses, expressly or under the principles of inherency, each and every element of a claimed invention. RCA Corp. v. Applied Digital Data Sys., Inc., 730 F.2d 1440, 1444, 221 USPQ 385, 388 (Fed. Cir. 1984). When the claimed invention is not identically disclosed in a reference, and instead requires picking and choosing among a number of different options disclosed by the reference, then the reference does not anticipate. Thus, the invention must have been known to the art in the detail of the claim; that is, all of the elements and limitations of the claim must be shown in a single prior reference, arranged as in the claim. See Karsten Mfg. Corp. v. Cleveland Gulf Co., 242 F.3d 1376, 1383, 58 USPQ2d 1286, 1291 (Fed. Cir. 2001); Akzo N.V. v. International Trade Commission, 808 F.2d 1471, 1480, 1 USPQ2d 1241, 1245-46 (Fed. Cir. 1986), cert. denied, 107 S.Ct. 2490 (1987); In re Arkley, 455 F.2d 586, 587-88, 172 USPQ 524, 526 (CCPA 1972).

B. The Analysis

The examiner's rejection does not follow the guidelines provided by the Courts. Claim 44 defines a method of coating an implantable medical device. The method includes the acts of (1) adding a copolymer of an ethylene comonomer with **a carboxylic acid** comonomer to a solvent system to form a composition, (2) applying the composition to an implantable medical device, and (3) allowing the solvent system to evaporate.

In contrast, Wang II describes forming a composition of ionomers that can form a film (col. 6, lines 17-63). The composition can be formed of three monomers: (a) an alpha-olefin, (b) **an ester** of alpha, beta-ethylenically-unsaturated carboxylic acid (see col. 2, lines 55 and 56), and (c) **a metal salt** of acrylic or methacrylic acid (col. 2, lines 55-59; col. 4, line 59 through col. 5, line 63).

Therefore, Wang II does not describe forming a coating including a copolymer of an ethylene comonomer with a carboxylic acid comonomer. A person of ordinary skill in the art can readily appreciate that **esters of a carboxylic acid and metal salts of a carboxylic acid are totally different chemical entities from the carboxylic acid.**

In the Office Action mailed on February 12, 2007, the examiner states that Wang II reads on the claims because the two compounds mentioned in the claim are part of a copolymer (page 3, middle paragraph). Applicant respectfully fails to see the relevance of this statement. Applicant can certainly see that Wang II describes a copolymer. However, **the copolymer described by Wang II is entirely different from the copolymer defined by claim 44** (see the discussion above).

In sum, claim 44 is not anticipated by Wang II under 35 U.S.C. §102(b). Claims 45, 46, 53 and 54 depend from claim 44 and are not anticipated by Wang II under 35 U.S.C. §102(b) for at least the same reason.

(2) Claims 47, 48 and 50-52 are non-obvious over Wang II in view of Chabrecek under 35 U.S.C. 103(a)

A. The Law

Claims are non-obvious if the claimed subject matter is more than a predictable use of prior art elements according to their established functions (see, KSR International Co. v. Teleflex, Inc., 550 U.S. ____, Slip Opinion No. 04-1350, page 13 (2007)).

Claims 47, 48 and 50-52 all depend from claim 44 and therefore all recite a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Wang II fails to provide for this copolymer (see the discussion above). Chabrecek describes a macromer that include a segmented copolymer, **which is an amide** (col. 1, line 20 through col. 2, line 23). Chabrecek describes toluene as a solvent but does not describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Therefore, Wang II and Chabrecek together do not teach the element "a copolymer of an ethylene comonomer with a carboxylic acid comonomer."

As mentioned previously, esters of a carboxylic acid and metal salts of a carboxylic acid are totally different chemical entities from the carboxylic acid. In addition, esters of a carboxylic acid and metal salts of a carboxylic acid have totally different physical and mechanical properties than the carboxylic acid. For example, as

an ordinary artisan would recognize, an ester of a carboxylic acid is more hydrophobic than the carboxylic acid. Conversely, a metal salt of the carboxylic acid is more hydrophilic than the carboxylic acid. A film formed of an ester of a carboxylic acid or a metal salt of a carboxylic acid would have totally different physical, mechanical, or drug release properties than a film formed of a carboxylic acid. A key aspect of the Wang II reference is to use a combination of an ester and metal salt of a carboxylic acid monomers for forming a film which has low haze (col. 1, lines 13-19), which attests to the different film properties different monomers in a polymer of the film can impart to the film. As such, to a person of ordinary skill in the art, a copolymer of an ethylene comonomer with a carboxylic acid comonomer as defined by any of claims 47, 48 and 50-52 is not a predictable variation of a copolymer formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of acrylic or methacrylic acid as described by Wang II.

Further, each of claims 47, and 50-52 includes limitations that carry additional patentability weight. Claim 47 further recites adding a therapeutic agent to the solvent system, and claims 50-55 require the carboxylic acid co-monomer content in the copolymer to be no less than 5% by weight and/or no more than 50% by weight.

In sum, claims 47, 48 and 50-52 are non-obvious over Wang II in view of Chabrecek under 35 U.S.C. 103(a)

(3) Claim 49 is non-obvious over Wang II in view of Kliment under 35 U.S.C. 103(a)

Claim 49 depends from claim 48, which recites a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Claim 49 further requires the solvent system to further comprise a chlorinated solvent and a lower alcohol.

Wang II is discussed above. Kliment describes a copolymer that can be dissolved in a chlorinated solvent. However, Kliment does not describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Therefore, Wang II and Kliment together do not teach the element, a copolymer of an ethylene comonomer with a carboxylic acid comonomer. As the above discussion shows, this copolymer is NOT a predictable variation of a copolymer formed of three monomers: (a) an alpha-olefin, (b) an ester of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) a metal salt of

acrylic or methacrylic acid as described by Wang II. Accordingly, claim 49 is non-obvious over Wang II in view of Kliment under 35 U.S.C. §103(a).

CONCLUSION

The examiner has failed, as a matter of law, to set forth a case of anticipation of claims 44-46 and 53-54 by Wang II under 35 U.S.C. 102(b).

The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 47, 48 and 50-52 under 35 U.S.C. 103(a) over Wang II in view of Chabrecek.

The examiner has failed, as a matter of law, to set forth a case of obviousness of claims 49 under 35 U.S.C. 103(a) over Wang II in view of Kliment.

Appellants therefore respectfully request that the Board reverse the rejections and order the application to be passed to issue.

Date: July 10, 2007

Respectfully submitted,

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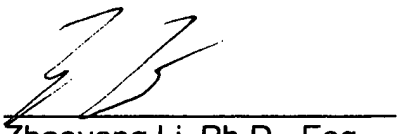

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CLAIMS APPENDIX

WHAT IS CLAIMED:

1-43. (Canceled).

44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid comonomer is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer no less than 5% by weight.

51. (Previously presented) The method of claim 50, wherein the carboxylic acid co-monomer has a content in the copolymer no more than 50% by weight.

52. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer no more than 50% by weight.

53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (Previously presented) The method of claim 44, wherein the device comprises a stent.

EVIDENCE APPENDIX

Attached hereto are the following:

(A) Office action mailed October 4, 2004;
(B) U.S. Patent No. 6,379,379 to Wang ("Wang ");
(C) U.S. Patent No. 4,142,526 to Zaffaroni et al. ("Zaffaroni");
(D) Response to Office Action filed on January 4, 2005;
(E) Office Action mailed on March 22, 2005;
(F) U.S. Patent No. 6,738,661 to Nyhart, Jr. ("Nyhart");
(G) Response to Office Action mailed on June 29, 2005;
(H) Notice of non-compliant amendment mailed on June 22, 2005;
(I) Response to Notice of non-compliant amendment mailed on July 7, 2005;
(J) Office Action mailed on September 29, 2005;
(K) U.S. Patent No. 5,401,512 to Rhodes ("Rhodes");
(L) Response to Office Action mailed on November 30, 2005;
(M) Notice of non-compliant amendment mailed on December 14, 2005;
(N) Response to Notice of non-compliant amendment mailed on January 6, 2006;
(O) Final Office Action mailed on March 22, 2006;
(P) Response to Final Office Action mailed on May 8, 2006;
(Q) Advisory Action mailed on May 25, 2006;
(R) Supplemental Response to Final Office Action mailed on June 2, 2006;
(S) Office Action mailed on August 24, 2006;
(T) U.S. Patent No. 5,631,328 to Wang et al. ("Wang II");
(U) U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek");
(V) U.S. Patent No.4,729,914 to Kliment et al. ("Kliment");
(W) Response to Office Action mailed on November 7, 2006;
(X) Final Office Action mailed on February 12, 2007; and
(Y) Advisory Action mailed on April 11, 2007.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 10/04/2004

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EXAMINER	
PHAN, HIEU	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response due 01/04/05

OCT 0 7 2004

BY ATTORNEY CALENDARED
SQUIRE, SANDERS & DEMPSEY

Office Action Summary	Application No.	Applicant(s)	
	10/712,678	MICHAL, GENE	
	Examiner	Art Unit	
	Hieu Phan	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Specification

1. The abstract of the disclosure is objected to because legal phraseology have been used. The legal terms "comprises" were used in the abstract and correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

3. Claims 37-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang (U.S. Patent 6,379,379) in view of Zaffaroni et al. (U.S. Patent 4,142,526).

Wang disclose a stent (10) made can be metal stent or polymeric stent having a coating contain drugs such as antithrombin or antiplatelet compounds as is claimed (Entire document but especially the following passages: Abstract, Figures 1-12, column 2 lines 26-67, column 3 lines 1-8 and 59-67, column 4 lines 1-34, column 5 lines 19-67 and column 6 lines 1-30). But Wang fails to disclose the carboxylic acid co-monomer content between 5-50 wt%.

Zaffaroni et al. teach an implant having a drug release coating with the carboxylic acid co-monomer content between 5-50 wt%. The advantage of having the carboxylic acid co-monomer content between 5-50 wt% is the release rate of the drugs can be vary by increase the co-monomer content.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the teaching of Zaffaroni et al. to modify the apparatus Wang to have the carboxylic acid co-monomer content between 5-50 wt%. The motivation for incorporating the feature of Zaffaroni et al. into the apparatus of Wang the release rate of the drugs can be vary by increase the co-monomer content.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 703-308-8969. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hieu Phan

FORM PTO-1449 (Modified) US DEPARTMENT OF COMMERCE
Approved for use through 10/31/2002 US Patent and Trademark Office

INFORMATION DISCLOSURE CITATION in an Application

(Use several sheets if necessary)

Docket No.	Application No.
50623.352	10/712,678
Applicant	
Gene Michal	
Filing Date	**Group Art Unit**
November 12, 2003	1615

U.S. PATENT DOCUMENTS

Examiner Initial	Ref. No.	Document Number	Date of Patent	Name	Class	Subclass	Filing Date if Appropriate
	A1	4,142,526	3/6/79	Zaffaroni et al.	424	424	3/9/77
	A2	4,329,383	5/11/82	Joh	428	36	7/21/80
	A3	4,733,665	3/29/88	Palmaz	128	343	11/7/85
	A4	4,800,882	1/31/89	Gianturco	128	343	3/13/87
	A5	4,882,168	11/21/89	Casey et al.	424	468	9/5/86
	A6	4,886,062	12/12/89	Wiktor	128	343	10/19/87
	A7	4,941,870	7/17/90	Okada et al.	600	36	12/30/88
	A8	4,977,901	12/18/90	Ofstead	128	772	4/6/90
	A9	5,112,457	5/12/92	Marchant	204	165	7/23/90
	A10	5,165,919	11/24/92	Sasaki et al.	424	488	9/26/90
	A11	5,272,012	12/21/93	Opolski	428	423.1	1/29/92
	A12	5,292,516	3/8/94	Viegas et al.	424	423	11/8/91
	A13	5,298,260	3/29/94	Viegas et al.	424	486	6/9/92
	A14	5,300,295	4/5/94	Viegas et al.	424	427	9/13/91
	A15	5,306,501	4/26/94	Viegas et al.	424	423	11/8/91
	A16	5,328,471	7/12/94	Slepian	604	101	8/4/93
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	A19	5,417,981	5/23/95	Endo et al.	424	486	4/28/93
	A20	5,447,724	9/5/95	Helmus et al.	424	426	11/15/93
	A21	5,455,040	10/3/95	Marchant	424	426	11/19/92
	A22	5,462,990	10/31/95	Hubbell et al.	525	54.1	10/5/93
	A23	5,464,650	11/7/95	Berg et al.	427	2.30	4/26/93
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	A27	5,609,629	3/11/97	Fearnot et al.	623	1	6/7/95
	A28	5,624,411	4/29/97	Tuch	604	265	6/7/95
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	A32	5,667,767	9/16/97	Greff et al.	424	9.411	7/27/95
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	A34	5,679,400	10/21/97	Tuch	427	2.14	6/7/95
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	A36	5,702,754	12/30/97	Zhong	427	2.12	2/22/95
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EXAMINER	DATE CONSIDERED 07/30/2004

EXAMINER: Initial if references considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Notice of References Cited	Application/Control No. 10/712,678	Applicant(s)/Patent Under Reexamination MICHAL, GENE	
	Examiner Hieu Phan	Art Unit 3738	Page 1 of 1

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	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

'A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gene Michal		Examiner: Hieu Phan	
Serial No.	10/712,678	Art Unit:	3738
Filed:	November 12, 2003		
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices		

Commissioner for Patents
USPTO
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Dear Examiner Phan:

This responds to the Office Action dated October 4, 2004.

Specification amendments begin at page 2.

Claim amendments begin at page3.

Remarks begin at page 5.

AMENDMENTS TO THE SPECIFICATION:

Please replace the abstract with the following replacement abstract:

> A coated stent is provided including a coating ~~comprising~~ composed of one or more co-polymers of ethylene with carboxylic acid wherein the carboxylic acid co-monomer content is 5-50 wt%.

Please replace the section entitled Cross Reference with the following replacement section:

Cross Reference

This is a divisional of U.S. patent application serial number 09/748,719 filed December 22, 2000, which issued on November 30, 2004 as U. S. Patent No. 6,824,559.

AMENDMENTS TO THE CLAIMS:

Replacement Claim Set:

37. (Previously Presented) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix.

38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.

42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

43. (Previously presented) The drug delivery matrix of claim 37, additionally comprising an implantable substrate wherein the copolymer is a coating on the implantable substrate.

44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or co-solvents.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 37-49 are pending.
- Claims 37-49 are rejected.

Applicant has amended the abstract as required by the Examiner.

Applicant has amended the Cross Reference section to indicate that the parent patent application has now issued as a patent.

These amendments are not new matter.

The Examiner has rejected Claims 37-49 under 35 U.S.C. § 103(a) as being unpatentable over Wang in view of Zaffaroni et al.

Applicant has thoroughly searched the disclosure of Zaffaroni et al. and cannot locate any place in Zaffaroni that teaches an ethylene-carboxylic acid copolymer. Nor can applicant find such a copolymer with 5-50 wt% of carboxylic acid monomer. Moreover, the only discussion directed at release rate in Zaffaroni appears to be directed at the ratio of acid hydrogen to esterified acidic hydrogen. Therefore, the cited combination does not teach every element of these claims. Furthermore, the Examiner has not provided facts supporting an advantage for combining the cited references; the Examiner has not indicated where that advantage is taught. Applicant do not know whether the Examiner is relying on some disclosure in Zaffaroni for this purported advantage or whether he is relying on the knowledge of one of ordinary skill in the art. If it is the former, Applicant asks that the Examiner point out where Zaffaroni teaches that advantage. If it the latter, the Examiner is taking official notice of the advantage. If so, Applicant traverses this act and asks for specific evidence that one of ordinary skill in the art would have recognized the advantage of combining the cited references. Applicant are entitled to make that request according MPEP §2144.03.

Furthermore, "in order to complete the PTO's prima facie case and shift the burden of going forward to applicant, there must be evidence (other than speculation by the PTO) that one of ordinary skill in the art would have been motivated to make the modification of the prior art necessary to arrive at the claimed subject matter." *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941, 1944 (Fed. Cir. 1992). Applicant asks for evidence to support the identified motivation.

Since prima facie obviousness has not been made out, please remove this rejection.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,

Date: January 4, 2005

Charles E. Runyan, Ph. D.
Attorney for Applicant
Reg. No. 43,066

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0235
crunyan@ssd.com

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on
Date: 01/04/05 By: Patricia Lemlib
Name of person signing certification

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,738,661 B1
DATED : May 18, 2004
INVENTOR(S) : Eldon H. Nyhart, Jr.

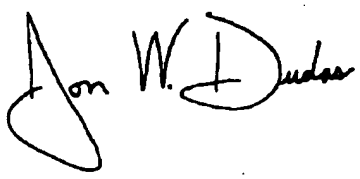
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 7,
Lines 59 and 63, please delete "C." and insert therefor -- C --.

Column 12,
Line 30, please delete "describe" and insert thereof -- described --.
Line 61, please delete "and" and insert thereof -- an --.

Signed and Sealed this

Fourth Day of January, 2005



JON W. DUDAS
Director of the United States Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 03/22/2005

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
PHAN, HIEU	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response Due 6/22/05
MAR 2 5 2005
BY NLP CALENDARED
ATTORNEY SQUIRE, SANDERS & DEMPSEY CR

Office Action Summary	Application No.	Applicant(s)	
	10/712,678	MICHAL, GENE	
	Examiner	Art Unit	
	Hieu Phan	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44-49* is/are allowed.

6)☒ Claim(s) *37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 37-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Nyhart, Jr. (U.S. Patent 6,738,661).

Nyhart, Jr disclosed a drug delivery matrix made of a copolymer of ethylene with carboxylic acid and a drug contained attached to the matrix as is claimed (column 7 lines 16-37).

Response to Arguments

3. Applicant's arguments, see paper 01/04/2005, filed 01/04/2005, with respect to claims 37-43 have been fully considered and are persuasive. The rejection of claim 37-43 in paper 10/04/2004 has been withdrawn.

Allowable Subject Matter

4. Claims 44-49 are allowed.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 571-272-4757. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hieu Phan
Examiner
Art Unit 3738

Notice of References Cited	Application/Control No. 10/712,678	Applicant(s)/Patent Under Reexamination MICHAL, GENE	
	Examiner Hieu Phan	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,948,529	09-1999	Hastie, Allan J.	428/373
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Gene Michal	Examiner:	Hieu Phan
Serial No.	10/712,678	Art Unit:	3738
Filed:	November 12, 2003		
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Dear Examiner Phan:

This responds to the Office Action dated March 22, 2005.

Claim set begin at page 2; no claims are amended.

Remarks begin at page 4.

AMENDMENTS TO THE CLAIMS:

Replacement Claim Set:

37. (Previously Presented) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix.

38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.

42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

43. (Previously presented) The drug delivery matrix of claim 37, additionally comprising an implantable substrate wherein the copolymer is a coating on the implantable substrate.

44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or co-solvents.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

REMARKS

Please reconsider this application in view of the above amendments and the following remarks.

- Claims 37-49 are pending.
- Claims 37-43 are rejected.
- Claims 44-49 are allowed.

Applicant thanks the Examiner for the indication of allowable subject matter.

The Examiner has rejected Claims 37-43 under 35 U.S.C. § 102(e) as being anticipated by Nyhart (U.S. Patent No. 6,738,661)—D1.

Applicant has thoroughly searched the disclosure of D1 and cannot locate any place in D1 that teaches an ethylene-carboxylic acid copolymer. Therefore, Claim 37 does not teach or disclose every element of Claim 37. Claims 37 is patentable over D1.

Claims 38-43 depend from Claim 37 and contain all the limitations of Claim 37. This makes these dependent claims patentable over D1 for at least the same reasons that were discussed for the independent claims. Please remove the rejection of these claims, as well.

Furthermore, Applicant can not find an ethylene-carboxylic acid copolymer with 5-50 wt% of carboxylic acid monomer, which means Claims 38-40 are patentable over D1 for this additional reason. Nor can Applicant find such a copolymer wherein the carboxylic acid is selected from the list recited in Claim 42 or wherein the copolymer is the copolymer recited in Claim 41. Therefore, Claims 41 and 42 are patentable over D1 for this additional reason.

Claims 37-43 are patentable over D1 because D1 does not teach each element of these claims. Please remove this rejection.

If the Examiner contends that Applicant has missed the relevant disclosure, Applicant asks that the Examiner point out where in the reference the relevant disclosure exits and asks for a definition of acronyms, if any, that are used, but not defined, in the relevant disclosure.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,

Date: June 22, 2005

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0235
crunyan@ssd.com

Charles E. Runyan, Ph. D.
Attorney for Applicant
Reg. No. 43,066

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 06/29/2005

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
PHAN, HIEU	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response Due 7/29/05

JUL 0 6 2005

BY MP CALENDARED CR
ATTORNEY
SQUIRE, SANDERS & DEMPSEY

10/712678

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 6/22/05 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required. **Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted.** 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
- ☐ B. New paragraph(s) should not be underlined.
- ☐ C. Other_____

☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
- ☐ B. Other_____

☐ 3. Amendments to the drawings: _____

☑ 4. Amendments to the claims:
- ☑ A. A complete listing of all of the claims is not present.
- ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
- ☑ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following 7 status identifiers: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New) and (Not entered).
- ☑ D. The claims of this amendment paper have not been presented in ascending numerical order.
- ☐ E. Other: _____

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT,** applicant is given ONE MONTH from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and **this ONE MONTH time limit is not extendable.**

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION (including a submission for an RCE),** and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION,** this form may be an attachment to an Advisory Action. **The period for response to a final rejection continues to run from the date set in the final rejection**, and is not affected by the non-compliant status of the amendment.

Linda Wrights 571-272-4397

Legal Instruments Examiner (LIE) Telephone No.

Rev. 6/04

Express Mail No. EV 721 157 250 US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gene Michal		Examiner: Hieu Phan	
Serial No.	10/712,678	Art Unit:	3738
Filed:	November 12, 2003		
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Dear Examiner Phan:

This responds to the Notice of Non-Compliant Amendment dated June 29, 2005.

Claim set begin at page 2; no claims are amended.

Remarks begin at page 4.

AMENDMENTS TO THE CLAIMS:

Replacement Claim Set:

1-36. (Canceled).

37. (Previously Presented) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix.

38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.

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44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or co-solvents.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

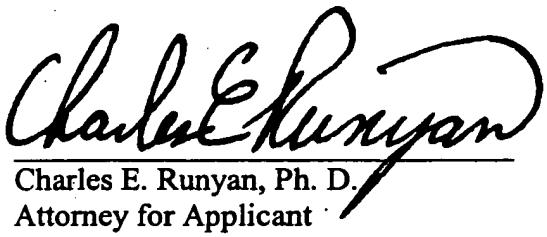
49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

REMARKS

Applicant re-submits the Amendments to the Claims Section. But also points out that Applicant amended no claims in the previous response and therefore Applicant provided the claim listing only as a convenience to the Examiner. Since Applicant made no amendment, the amendment was not non-compliant.

Since all claims are in a condition for allowance, please issue a Notice of Allowability so stating. If I can be of any help, please contact me.

Respectfully submitted,



Date: July 7, 2005

Charles E. Runyan, Ph. D.
Attorney for Applicant
Reg. No. 43,066

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
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crunyan@ssd.com

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590 09/29/2005

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
PHAN, HIEU	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response Due 12/29/05

OCT 0 3 2005

BY EO CALENDARED

ATTORNEY BP

SQUIRE, SANDERS & DEMPSEY

Office Action Summary	Application No.	Applicant(s)	
	10/712,678	MICHAL, GENE	
	Examiner	Art Unit	
	Hieu Phan	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44-49* is/are allowed.

6)☒ Claim(s) *37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512).

Rhodes et al. disclosed a drug delivery matrix made of a copolymer of ethylene with carboxylic acid and a drug contained attached to the matrix as is claimed (column 1 lines 41-68 and column 2 lines 1-6).

Response to Arguments

3. Applicant's arguments see paper 01/04/2005, filed 03/22/2005, with respect to claims 37-43 have been fully considered and are persuasive. The rejection of claim 37-43 in paper 03/22/2005 has been withdrawn.

Allowable Subject Matter

4. Claims 44-49 are allowed.

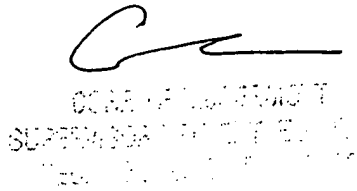
Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hieu Phan whose telephone number is 571-272-4757. The examiner can normally be reached on Monday-Friday from 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hieu Phan
Examiner
Art Unit 3738



Notice of References Cited	Application/Control No. 10/712,678	Applicant(s)/Patent Under Reexamination MICHAL, GENE	
	Examiner Hieu Phan	Art Unit 3738	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,401,512	03-1995	Rhodes et al.	424/458
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gene Michal		Examiner: Hieu Phan	
Serial No.	10/712,678	Art Unit:	3738
Filed:	November 12, 2003		
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Dear Examiner Phan:

This is a response to the Office Action dated September 29, 2005, which has a shortened statutory period for reply that is set to expire on December 29, 2005.

Amendments to Claims begin at page 2.

Remarks begin at page 5.

AMENDMENTS TO THE CLAIMS:

1-36. (Canceled).

37. (Currently amended) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate.

38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

41. (Previously presented) The drug delivery matrix of claim 37, wherein the copolymer is ethylene acrylic acid.

42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

43. (Canceled).

44. (Allowed) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Allowed) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Currently amended) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent ~~co-solvents~~.

47. (Allowed) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Allowed) The method of claim 44, wherein the solvent system comprises toluene.

49. (Allowed) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

51. (New) The method of claim 50, wherein the carboxylic acid co-monomer content

is no more than 50% by weight.

52. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

53. (New) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (New) The method of claim 44, wherein the device comprises a stent.

55. (New) The drug delivery matrix of claim 37, wherein the implantable substrate comprises at least a portion of a stent body.

REMARKS

Claim Rejections – 35 U.S.C. § 102

Please reconsider the application in view of the remarks set out below.

Claims 37-42 and 44-55 are pending.

Claims 50-55 are new.

Claims 44-49 have been allowed.

Claim 43 is now canceled.

Claims 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512), ("Rhodes").

Amended, independent Claim 37 recites, "A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate."

Rhodes fails to teach or suggest that the "copolymer is a coating on an implantable substrate" as recited by amended, independent Claim 1 of the present invention. Rather, Rhodes provides "an orally administrable formulation for selectively administering the drug to the large intestine" (Column 1, line 44-46). Since Rhodes fails to teach or suggest all the limitations of Claim 37, Claim 37 and claims dependent thereon are in condition for allowance.

Conclusion

Claims 37-42 and 44-55 are pending in this application. Claims 37-42 have been placed in condition for allowance. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: November 30, 2005

Angie M. Augustus
Attorney for Applicant
Reg. No. 51,421

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0200

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 12/14/2005

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
PHAN, HIEU	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response due 1/14/05

DEC 19 2005

CALENDARED

BY EQ
ATTORNEY AMA
SQUIRE, SANDERS & DEMPSEY

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

Notice of Non-Compliant Amendment (37 CFR 1.121)

The amendment document filed on 11/30/05 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required. **Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted.** 37 CFR 1.121(h).

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
- ☐ B. New paragraph(s) should not be underlined.
- ☐ C. Other_____

☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
- ☐ B. Other_____

☐ 3. Amendments to the drawings: _____

☑ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
- ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
- ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following 7 status identifiers: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New) and (Not entered).
- ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
- ☑ E. Other: THE WORD ALLOWED IS NOT THE PROPER STATUS IDENTIFIER

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP Sec. 714 and the USPTO website at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf.

If the non-compliant amendment is a **PRELIMINARY AMENDMENT,** applicant is given ONE MONTH from the mail date of this letter to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and **this ONE MONTH time limit is not extendable.**

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION (including a submission for an RCE),** and since the amendment appears to be a *bona fide* attempt to be a reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

If the amendment is a reply to a **FINAL REJECTION,** this form may be an attachment to an Advisory Action. **The period for response to a final rejection continues to run from the date set in the final rejection,** and is not affected by the non-compliant status of the amendment.

Stefanie Bryce — 571-272-4334

Legal Instruments Examiner (LIE) — Telephone No.

STEFANIE BRYCE

Rev. 6/04

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 12/14/2005

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

EXAMINER	
PHAN, HIEU	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

DATES ENTERED Response due 1/14/05

DEC 19 2005

CALENDARED

BY EQ
ATTORNEY AMA
SQUIRE, SANDERS & DEMPSEY

Notice of Non-Compliant Amendment (37 CFR 1.121)	10712678	Applicant(s)	
	Examiner	Art Unit	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 11/30/05 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
  - ☐ A. Amended paragraph(s) do not include markings.
  - ☐ B. New paragraph(s) should not be underlined.
  - ☐ C. Other
- ☐ 2. Abstract:
  - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
  - ☐ B. Other_____.
- ☐ 3. Amendments to the drawings:
  - ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
  - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
  - ☐ C. Other_____.
- ☒ 4. Amendments to the claims:
  - ☐ A. A complete listing of all of the claims is not present.
  - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
  - ☒ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
  - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
  - ☒ E. Other: "Allowed" is not proper status identifier.
- ☐ 5. The amendment is unsigned or not signed in accordance with 37 CFR 1.4.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf .

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

1. Applicant is given **no new time period** if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the **entire corrected amendment** must be resubmitted within the time period set forth in the final Office action.
2. Applicant is given **one month**, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the **corrected section** of the non-compliant amendment in compliance with 37 CFR 1.121 or 1.4, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a *Quayle* action.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action.
Failure to timely respond to this notice will result in:
Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a *Quayle* action; or
Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

R.Johnson — 571-272-4359

~~Legal Instruments Examiner (LIE)~~ — ~~Telephone No.~~

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gene Michal		Examiner: Hieu Phan
Serial No.	10/712,678	Art Unit: 3738
Filed:	November 12, 2003	
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTICE OF NON-COMPLAINT AMENDMENT

Dear Examiner Phan:

This is a response to the Notice of Non-Complaint Amendment dated December 14, 2005, which has a shortened statutory period for reply that is set to expire on January 14, 2006.

Amendments to the Claims begin at page 2.

Remarks begin at page 5.

AMENDMENTS TO THE CLAIMS:

1-36. (Canceled).

37. (Currently amended) A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate.

38. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

39. (Previously presented) The drug delivery matrix of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

40. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

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42. (Previously presented) The drug delivery matrix of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

43. (Canceled).

44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Currently amended) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent ~~co-solvents~~.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

51. (New) The method of claim 50, wherein the carboxylic acid co-monomer content

is no more than 50% by weight.

52. (New) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

53. (New) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (New) The method of claim 44, wherein the device comprises a stent.

55. (New) The drug delivery matrix of claim 37, wherein the implantable substrate comprises at least a portion of a stent body.

REMARKS

Claim Rejections – 35 U.S.C. § 102

Please reconsider the application in view of the remarks set out below.

Claims 37-42 and 44-55 are pending.

Claims 50-55 are new.

Claims 44-49 have been allowed.

Claim 43 is now canceled.

Claims 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512), ("Rhodes").

Amended, independent Claim 37 recites, "A drug delivery matrix, comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the matrix, wherein the copolymer is a coating on an implantable substrate."

Rhodes fails to teach or suggest that the "copolymer is a coating on an implantable substrate" as recited by amended, independent Claim 1 of the present invention. Rather, Rhodes provides "an orally administrable formulation for selectively administering the drug to the large intestine" (Column 1, line 44-46). Since Rhodes fails to teach or suggest all the limitations of Claim 37, Claim 37 and claims dependent thereon are in condition for allowance.

Conclusion

Claims 37-42 and 44-55 are pending in this application. Claims 37-42 have been placed in condition for allowance. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: January 6, 2006

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
Telephone (415) 954-0200

Angie M. Augustus
Attorney for Applicant
Reg. No. 51,421

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 03/22/2006

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

DOCKETED: FINAL OFFICE ACTION
due 6/22/06

MAR 27 2006

BY: JDB Atty: AMA

SQUIRE, SANDERS & DEMPSEY

EXAMINER	
STEWART, ALVIN J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/712,678	Applicant(s) MICHAL, GENE	
	Examiner Alvin J. Stewart	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-42 and 44-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44-54* is/are allowed.

6)☒ Claim(s) *37-42 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-42 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al US Patent 5,401,512.

Rhodes et al discloses a drug delivery matrix made of a copolymer of ethylene with carboxylic acid and a drug contained attached to the matrix (see col. 1, lines 41-68 and col. 2, lines 1-6).

Response to Arguments

Applicant's arguments filed January 06, 2006 have been fully considered but they are not persuasive. The Examiner noticed the new limitations entered in claim 37. However, the Examiner has not given patentable weight to the "wherein" clause because a "wherein" clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim. *See Texas Instruments Inc. v. International Trade Commision, 26 USPQ2d 1010 (Fed. Cir. 1993); Griffin v. Bertina, 62 USPQ2d 1431 (Fed. Cir. 2002); Amazon.com Inc. v. Barnesandnoble.com Inc., 57 Uspq2d 1747 (Fed. Cir. 2001).*

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Stewart

Art Unit 3738

ALVIN J. STEWART
PRIMARY EXAMINER

March 20, 2006.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gene Michal		Examiner: Alvin J. Stewart
Serial No.	10/712,678	Art Unit: 3738
Filed:	November 12, 2003	
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices	

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

Dear Examiner Stewart:

This is a response to the Final Office Action dated March 22, 2006, which has a shortened statutory period for reply that is set to expire on June 22, 2006.

Amendments to the Specification begin at page 2.

Amendments to the Claims begin at page 3.

Remarks begin at page 6.

AMENDMENTS TO THE SPECIFICATION

Please amend page 13, lines 8-12 as follows:

A polycarbonate-urethane material such as Bionate 80 is very hygroscopic. Pellets of Bionate 80 are dried by a process, such as with a forced air dehumidifying dryer at 82 degrees ~~C,~~ ~~For~~ C for at least about 4 hours prior to extrusion or injection molding. Bionate 80 pellets are typically filtered during extrusion~~, though~~ through filters such as a 350 mesh filter and two 500 mesh filters.

AMENDMENTS TO THE CLAIMS:

1-36. (Canceled).

37. (Currently amended) A drug delivery ~~matrix,~~ coating on an implantable medical device, the coating comprising a copolymer of ethylene with carboxylic acid and a drug contained within or attached to the coating ~~matrix, wherein the copolymer is a coating on an implantable substrate~~.

38. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

39. (Currently amended) The drug delivery ~~matrix~~ coating of claim 38, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

40. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

41. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the co-polymer is ethylene acrylic acid.

42. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

43. (Canceled).

44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (Previously presented) The method of claim 44, wherein the carboxylic acid comonomer content is no less than 5% by weight.

51. (Previously presented) The method of claim 50, wherein the carboxylic acid comonomer content is no more than 50% by weight.

52. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (Previously presented) The method of claim 44, wherein the device comprises a stent.

55. (Currently amended) The drug delivery ~~matrix~~ coating of claim 37, wherein the implantable substrate comprises at least a portion of a stent body.

REMARKS

Claim Rejections – 35 U.S.C. § 102

Please reconsider the application in view of the remarks set out below.

Claims 37-42 and 44-55 are pending.

Claims 37-42, 55 are currently amended.

Claims 44-54 have been allowed.

Claim 43 has been canceled.

Claims 37-43 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes et al. (U.S. Patent 5,401,512), ("Rhodes").

The Examiner has not given patentable weight to the "wherein" clause, "because a 'wherein' clause that merely states the result of the limitations in the claim adds nothing to the patentability or substance of the claim" (Office Action, Page 2).

In response, Applicants have amended Claim 37 to clarify that an implantable device is patentably or substantively part of Claim 37. Please reconsider arguments presented below in light of this amendment.

Amended Claim 37 now recites, "**A drug delivery coating on an implantable substrate...**"

Rhodes fails to teach or suggest that the "**A drug delivery coating on an implantable substrate...**" as recited by Amended Claim 37. Rather, Rhodes discloses "an orally administrable formulation for selectively administering the drug to the large intestine" (Column 1, line 44-46). Since Rhodes fails to teach or suggest all the limitations of Claim 37, Claim 37 and dependent Claims 38-42 and 55, are in condition for allowance.

CONCLUSION

Claims 37-42 and 44-55 are pending in this application. Claims 44-54 have been allowed. Claims 37-42 and 55 are now in condition for allowance. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: May 8, 2006

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza
Suite 300
San Francisco, CA 94111
Facsimile (415) 393-9887
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Angie M. Augustus
Attorney for Applicant
Reg. No. 51,421

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 05/25/2006

EXAMINER	
STEWART, ALVIN J	
ART UNIT	PAPER NUMBER
3738	

Cameron K. Kerrigan
Squire, Sanders & Dempsey L.L.P.
Suite 300
1 Maritime Plaza
San Francisco, CA 94111

DOCKETED: see below

MAY 31 2006

BY: TTB Atty: AMA
SQUIRE, SANDERS & DEMPSEY

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

ADVISORY ACTION - due 6/22/06
w/ 1 mo. extension - 7/22/06
w/ 2 mo. extension - 8/22/06
DROP DEAD DATE - 9/22/06

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/712,678	Applicant(s) MICHAL, GENE	
	Examiner Alvin J. Stewart	Art Unit 3738	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *44-54*.
   Claim(s) objected to: _____.
   Claim(s) rejected: *37-42 and 55*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER
Art Unit: 3738

Continuation of 3. NOTE: The new limitations are positively claiming a coating. For the above reasons, the new limitations required a further consideration.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gene Michal		Examiner: Alvin J. Stewart	
Serial No.	10/712,678	Art Unit:	3738
Filed:	November 12, 2003		
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices		

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL RESPONSE TO OFFICE ACTION

Dear Examiner Stewart:

This is a supplemental response to the Final Office Action dated March 22, 2006, which has a shortened statutory period for reply that is set to expire on June 22, 2006. Since the last response to the final office action was not entered, Applicants believes that they have used the correct claim identifiers and are resubmitting the amendment to the specification.

AMENDMENTS TO THE SPECIFICATION

Please amend page 13, lines 8-12 as follows:

A polycarbonate-urethane material such as Bionate 80 is very hygroscopic. Pellets of Bionate 80 are dried by a process, such as with a forced air dehumidifying dryer at 82 degrees ~~C,~~ ~~For~~ C for at least about 4 hours prior to extrusion or injection molding. Bionate 80 pellets are typically filtered during extrusion~~, though~~ through filters such as a 350 mesh filter and two 500 mesh filters.

AMENDMENTS TO THE CLAIMS:

1-43. (Canceled).

44. (Previously presented) A method of coating an implantable medical device, comprising:

adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Previously presented) The method of claim 44, wherein the carboxylic acid is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system further comprises a chlorinated solvent and a lower alcohol.

50. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer content is no less than 5% by weight.

51. (Previously presented) The method of claim 50, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

52. (Previously presented) The method of claim 44, wherein the carboxylic acid co-monomer content is no more than 50% by weight.

53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (Previously presented) The method of claim 44, wherein the device comprises a stent.

55. (Canceled)

REMARKS

Claims 44-54 have been allowed. Claims 37-42 and 55 are canceled by this response. Applicant respectfully requests the Examiner to enter the foregoing amendments and issue a Notice of Allowability. If I can be of any help in any way, please contact me.

Respectfully submitted,

Date: June 2, 2006

Squire, Sanders & Dempsey L.L.P.
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Cameron Kerrigan
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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 08/24/2006

Cameron K. Kerrigan
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Suite 300
1 Maritime Plaza
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DOCKETED: due 11/24/06

AUG 29 2006

BY: fjb Atty: AMA
SQUIRE, SANDERS & DEMPSEY

EXAMINER
STEWART, ALVIN J

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,678	MICHAL, GENE	
	Examiner	Art Unit	
	Alvin J. Stewart	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 50-52 recite the limitation "carboxylic acid comonomer" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-46 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al US Patent 5,631,328.

Wang et al discloses a method of making a coat having the step of adding a copolymer of ethylene with carboxylic acid to a solvent system to form a composition (see col. 2, lines 52-60); applying the composition to an implantable medical device (see col. 17, lines 38-42) and allowing the solvent system to evaporate (see col. 8, lines 62-65).

Regarding claim 45, see col. 3, lines 43 and 54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 47, 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Chabrecek et al US Patent 6,087,412.

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a solvent system made of toluene.

Chabrecek et al discloses a solvent made of toluene for the purpose of having an inert solvent (see col. 9, lines 65-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the solvent of the Wang et al reference with the toluene solvent of the Chabrecek et al reference in order to have an inert solvent.

Regarding claims 50-52, disclose the claimed invention except for having a carboxylic acid comonomer between 5 to 50 percent by weight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the percentage by weight of the copolymer, since it has been held that finding an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Kliment et al US Patent 4,729,914.

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a chlorinated solvent.

Kliment et al teaches a copolymer having a solvent and the solvent is chlorinate for the purpose of obtaining an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures (see col. 4, lines 4-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Wang et al reference with the Kliment reference in order to obtain an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER
Art Unit 3738

August 7, 2006.

Notice of References Cited

Application/Control No.	Applicant(s)/Patent Under Reexamination	
10/712,678	MICHAL, GENE	
Examiner	Art Unit	Page 1 of 1
Alvin J. Stewart	3738	

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-4,729,914	03-1988	Kliment et al.	428/35.7
*	B	US-5,631,328	05-1997	Wang et al.	525/329.7
*	C	US-6,087,412	07-2000	Chabrecek et al.	522/35
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Gene Michal		Examiner: Alvin J. Stewart	
Serial No.	10/712,678	Art Unit:	3738
Filed:	November 12, 2003		
Title:	Ethylene-Carboxyl Copolymers As Drug Delivery Matrices		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND RESPONSE TO OFFICE ACTION

Dear Examiner Stewart:

This is a response to the Office Action mailed on August 24, 2006.

IN THE CLAIMS

1-43. (Canceled).

44. (Currently amended) A method of coating an implantable medical device, comprising:

adding a copolymer of an ethylene comonomer with a carboxylic acid comonomer to a solvent system to form a composition;

applying the composition to an implantable medical device; and

allowing the solvent system to evaporate.

45. (Currently amended) The method of claim 44, wherein the carboxylic acid comonomer is selected from a group consisting of acrylic acid, methacrylic acid, maleic acid, itocanic acid, and esters thereof.

46. (Previously presented) The method of claim 44, wherein adding the copolymer to the solvent system further comprises neutralizing the copolymer in a volatile or a non-volatile base and dispersing the copolymer in water and/or a co-solvent.

47. (Previously presented) The method of claim 44, further comprising adding a therapeutic agent to the solvent system.

48. (Previously presented) The method of claim 44, wherein the solvent system comprises toluene.

49. (Previously presented) The method of claim 48, wherein the solvent system fur-

ther comprises a chlorinated solvent and a lower alcohol.

50. (Currently amended) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer ~~is~~ no less than 5% by weight.

51. (Currently amended) The method of claim 50, wherein the carboxylic acid co-monomer has a content in the copolymer ~~is~~ no more than 50% by weight.

52. (Currently amended) The method of claim 44, wherein the carboxylic acid co-monomer has a content in the copolymer ~~is~~ no more than 50% by weight.

53. (Previously presented) The method of claim 44, wherein the co-polymer is ethylene acrylic acid.

54. (Previously presented) The method of claim 44, wherein the device comprises a stent.

55. (Canceled)

REMARKS

Claims 44-54 are pending. Claims 44-54 are rejected. For record, claims 44-54 were previously allowed. Claims 37-42 and 55 were canceled.

Rejections under 35 U.S.C. §112, second paragraph

Claims 50-52 have been rejected as being indefinite under 35 U.S.C. §112, second paragraph, for allegedly failing to provide an antecedent basis for "carboxylic acid co-monomer." Applicants believe the amendment in this response cures the rejections.

Rejections under 35 U.S.C. §102

Claims 44-46 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,631,328 to Wang et al. ("Wang").

Claim 44 defines a method of coating an implantable medical device. The method comprising (1) adding a copolymer of an ethylene comonomer with **a carboxylic acid comonomer** to a solvent system to form a composition, (2) applying the composition to an implantable medical device, and (3) allowing the solvent system to evaporate.

Wang describes forming a composition of ionomers that can form a film (col. 6, lines 17-63). The composition can be formed of three monomers: (a) an alpha-olefin, (b) **an ester** of alpha, beta-ethylenically-unsaturated carboxylic acid, and (c) **a metal salt** of acrylic or methacrylic acid (col. 4, line 59 through col. 5, line 63). **Wang does not describe forming a coating including a copolymer of an ethylene comonomer with a carboxylic acid comonomer. Esters of a carboxylic acid and metal salts of a carbox-**

ylic acid are totally different chemical entities from the carboxylic acid. In addition, esters of a carboxylic acid and metal salts of a carboxylic acid have totally different physical and mechanical properties than the carboxylic acid. For example, as an ordinary artisan would recognize, an ester of a carboxylic acid is more hydrophobic than the carboxylic acid. Conversely, a metal salt of the carboxylic acid is more hydrophilic than the carboxylic acid. A film formed of an ester of a carboxylic acid or a metal salt of a carboxylic acid would have totally different physical, mechanical, or drug release properties than a film formed of a carboxylic acid. A key aspect of the Wang reference is to use a combination of an ester and metal salt of a carboxylic acid monomers for forming a film which has low haze (col. 1, lines 13-19), which attests to the different film properties that different monomers in a polymer of the film can impart to the film.

Accordingly, claim 44 is patentably allowable over Wang. Claims 45, 46, 53 and 54 depend from claim 44 and are patentably allowable over Wang for at least the same reason.

Rejections under 35 U.S.C. §103

Claims 47, 48, and 50-52 are rejected under 35 U.S.C. 103(a) as being obvious over Wang in view of U.S. Patent No. 6,087,412 to Chabrecek et al. ("Chabrecek").

Claims 47, 48 and 50-52 depend from claim 44, which is discussed above, and therefore require a copolymer of an ethylene comonomer with a carboxylic acid comonomer.

Chabrecek describes a macromer that include a segmented copolymer which is an

amide (col. 1, line 20 through col. 2, line 23). Chabrecek does not **describe a copolymer of an ethylene comonomer with a carboxylic acid comonomer.** Therefore, Chabrecek does not cure the deficiencies of Wang, which is discussed above. Therefore, claims 47, 48 and 50-52 are patentably allowable over Wang in view of Chabrecek.

Claim 49 is rejected as being obvious over Wang in view of U.S. Patent No. 4,729,914 to Kliment et al. ("Kliment").

Claim 49 depends from claim 44, which is discussed above, and therefore requires **a copolymer of an ethylene comonomer with a carboxylic acid comonomer**.

Kliment describes forming an N-vinylpyrrolidone copolymer that can include ethylenic monomers such as hydroxylethyl methacrylate or hydroxylpropyl acrylate. **Hydroxylethyl methacrylate or hydroxylpropyl acrylate is an ester of methacrylate or acrylate, which is not a carboxylic acid monomer** (see the discussion of Wang, *supra*). Therefore, Kliment does not describe **a copolymer of an ethylene comonomer with a carboxylic acid comonomer** and thus does not cure the deficiency of Wang. Accordingly, claim 49 is patentably allowable over Wang in view of Kliment.

The undersigned authorizes the examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

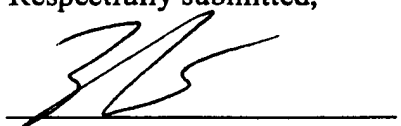
CONCLUSIONS

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

Date: November 7, 2006

Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111
Telephone (415) 393-9885
Facsimile (415) 393-9887

Respectfully submitted,



Zhaoyang Li, Ph.D.
Reg. No. 46,872

23980

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 02/12/2007

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DOCKETED: FINAL REJECTION

FEB 15 2007

BY: tjb Atty: PL

SQUIRE, SANDERS & DEMPSEY

EXAMINER	
STEWART, ALVIN J	
ART UNIT	**PAPER NUMBER**
3738	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

FINAL OFFICE ACTION
RESPONSE DUE: 5/12/07
NTC of APPEAL DUE: 8/12/07

Office Action Summary	Application No.	Applicant(s)	
	10/712,678	MICHAL, GENE	
	Examiner	Art Unit	
	Alvin J. Stewart	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 0706*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

Applicant's arguments filed 11/07/07 have been fully considered but they are not persuasive.

The meaning of the word comonomer is the following: one of the compounds that constitute a copolymer. Therefore, the Examiner believes that the reference still reads on the claims because the two compounds mentioned in the claim are part of a copolymer.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the word carboxylic acid comonomer is not disclosed in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The word ethylene comonomer is not disclosed in the specification. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 44-46 and 53-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al US Patent 5,631,328.

Wang et al discloses a method of making a coat having the step of adding a copolymer of comonomer ethylene with a carboxylic acid comonomer to a solvent system to form a composition (see col. 2, lines 52-60); applying the composition to an implantable medical device (see col. 17, lines 38-42) and allowing the solvent system to evaporate (see col. 8, lines 62-65). The meaning of the word comonomer is the following: one of the compounds that constitute a copolymer. Therefore, the Examiner believes that the reference still reads on the claims because the two compounds mentioned in the claim are part of a copolymer.

Regarding claim 45, see col. 3, lines 43 and 54.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 47, 48 and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Chabrecek et al US Patent 6,087,412.

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a solvent system made of toluene.

Chabrecek et al discloses a solvent made of toluene for the purpose of having an inert solvent (see col. 9, lines 65-67).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the solvent of the Wang et al reference with the toluene solvent of the Chabrecek et al reference in order to have an inert solvent.

Regarding claims 50-52, disclose the claimed invention except for having a carboxylic acid comonomer between 5 to 50 percent by weight. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the percentage by weight of the copolymer, since it has been held that finding an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980).

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al US Patent 5,631,328 in view of Kliment et al US Patent 4,729,914.

Wang et al discloses the invention substantially as claimed. However, Wang et al does not disclose a chlorinated solvent.

Kliment et al teaches a copolymer having a solvent and the solvent is chlorinate for the purpose of obtaining an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures (see col. 4, lines 4-14).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Wang et al reference with the Kliment reference in order to

obtain an organic liquid which is relatively easy to evaporate at room or slightly elevated temperatures.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER
Art Unit 3738

February 02, 2007.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,678	11/12/2003	Gene Michal	50623.352	9070

7590 04/11/2007

Cameron K. Kerrigan
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EXAMINER	
STEWART, ALVIN J	

ART UNIT	PAPER NUMBER
3738	

MAIL DATE	DELIVERY MODE
04/11/2007	PAPER

ADVISORY ACTION

RESPONSE DUE: 5/12/07
w/ 1 MONTH EXT: 6/12/07
w/ 2 MONTH EXT: 7/12/07
DROP DEAD DATE: 8/12/07

Please find below and/or attached an Office communication concerning this application or proceeding.

DOCKETED: _____

APR 17 2007

BY: JB Atty: ZL

SQUIRE, SANDERS & DEMPSEY

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/712,678	Applicant(s) MICHAL, GENE	
	Examiner Alvin J. Stewart	Art Unit 3738	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

A. Stewart

ALVIN J. STEWART
PRIMARY EXAMINER
Art Unit: 3738

Continuation of 11. does NOT place the application in condition for allowance because: The Examiner stil believes that the previous rejection is proper. No new limitations have been entered.

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

Deleted: SANFRANCISCO/224926.1 ¶
06/27/07

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